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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,395	05/07/2001	Yasuo Sakai	SUD-001-USA-CIP	9441

7590 02/09/2004

Townsend & Banta  
Suite 900 South Building  
601 Pennsylvania Avenue N W  
Washington, DC 20004

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

09/849,395

## Applicant(s)

SAKAI ET AL.

## Examiner

Gary B. Nickol Ph.D.

## Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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Re: Sakai *et al.*

Date of Priority: 12/27/1995

***Response to Amendment***

The Amendment filed November 14, 2003 in response to the Office Action of May 14, 2003 is acknowledged and has been entered.

Claims 8-9 were added.

Claims 1-9 are currently pending and are under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**New Rejections:**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation of a nonantigenic stabilizer that comprises "70 wt% or more of a single peptide chain having a molecular weight of from greater than 1000" does not appear to have clear support in the specification and the claims as originally filed. Specifically, the specification does not appear to contemplate a "wt%"; a "single peptide chain"; or "from greater than 1,000" (Claims 1, 3, 5-7). Additionally, the language of "wherein said nonantigenic stabilizer is not bonded with any other compound, does not have a triple helix structure, and no transition temperature is observed (Claims 5, 7) fails to find support in the disclosure as originally filed. Further, there is no support in the disclosure for a nonantigenic stabilizer that comprises from 0.005 to 15 wt% of a physiologically active substance (Claims 8-9). Hence, this is a **new matter** rejection. Applicants argue (Remarks, page 5) that support for the amendments and new claims can be found in the specification on page 3, line 25 to page 4, line 1; page 5, lines 5-8, and page 5, lines 16-18. This argument has been considered but is not found persuasive, as the suggested support could not be found. For example, with regards to new claims 8 and 9, the specification teaches (page 5, 3<sup>rd</sup> para.) that the physiologically active substance involved in the present invention is "characterized by containing 0.005-15 percent by weight of the nonantigenic stabilizer" which is not equivalent to a nonantigenic stabilizer that comprises from 0.005 to 15 wt% of a physiologically active substance, as claimed. Also, with regards to the language of "from greater than 1,000", the specification only appears to contemplate (page 5) preparation of the stabilizer with a higher yield from the same raw material than that with a molecular weight of "not more than 1000" which does not appear to parallel the instant claims drawn to a stabilizer

that has a molecular weight of from greater than 1,000 to not more than 20,000 Da. Thus, the newly amended claims appear to comprise new matter.

*In the event that applicant's response to this action results in the amendment of the claims to cancel the new matter, the prior art rejections of record in the Action mailed (05/14/03) will be re-instated.*

**All other rejections and or objections are withdrawn in view of applicant's amendments there to.**

**No claim is allowed.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143.

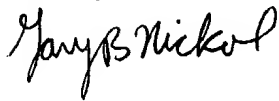
The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.  
Examiner  
Art Unit 1642

GBN  
January 29, 2004

A handwritten signature in cursive script, appearing to read "Gary B. Nickol".